IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Tiedje et al.
Serial No.: 10/073,464 Art Unit: 1634
Filed: 02/11/202 Examiner: Bausch, S.
Entitled: **Microbial Identification Chip Based On DNA-DNA Hybridization**

DECLARATION OF DR. JAMES TIEDJE UNDER 37 CFR § 1.132

Mail Stop –Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: October 18, 2007 By: Traci E. Light

Examiner Bausch:

I, James Tiedje, Ph.D. under penalty of perjury, state that:

1. I am an inventor of the embodiments of the invention as claimed in the United States patent application captioned above.

2. I am considered an expert in the field of microarrays and microbial species identification using gene sequencing technology.

3. I understand that the Examiner believes that Kuiipers, *Current Opin In Biotechnology* 10:511-516 (1999) describes a method of bacterial identification that is similar to my patent application. I have read and understood Kuipers and disagree with the Examiner.

4. Kuipers clearly specifies that genes with a known sequence must be placed on a microarray for their method to be useful. For example, at col 2, page 512, Kuipers refers to the use of open reading frames (ORF) and cDNAs made from mRNAs. Kuipers also provides a table (Table 1) and stresses that, with more sequencing completed, more known sequences can be arrayed.

5. The method described in my patent application avoids the necessity of having to know the nucleic acid sequences before a microarray is used and employs random genomic fragments. By comparing binding patterns between labeled nucleotides from various known bacterial species and labeled nucleotides from an unknown species, the requirement for knowing the nucleic acid sequences from the known bacterial species is unnecessary. The current official standard of bacterial species determination now recognizes that a 70% DNA-DNA hybridization pattern is sufficient to identify an unknown species.

6. The ability to identify bacterial species without requiring knowing the sequences of all the nucleic acids on the microarray has clear advantages. From a practical point of view, our approach takes less time to prepare the microarray. Further, the microarrays are more economical since the microarrayed nucleic acids do not have to be purchased and/or sequenced before use. Also, our method increases the flexibility of the microarrays. Previous techniques are limited to identifying bacterial species whose genome, or significant number of genes, has already been sequenced. Our method allows identification of microbial species for which genome sequence is unknown.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

Dated: October 18, 2007

Dr. James Tiedje